

Purpose: To define basic properties of the duplex ultrasound diagnostic test for reflux in veins of lower extremities, and to examine if some of the elements of this test can be standardized in order to improve reproducibility.

Methods: This is a prospective multi-center study sponsored by the American Venous Forum Foundation. Vascular laboratories from 11 centers participated in protocol development, educational intervention, and data collection.

Repeatability studies were performed as a duplicate test within 2 weeks between replicates performed by the same technologist, at the same time of the day, using the same reflux provoking maneuver, and with patient at the same position. Repeatability was separately examined for different combinations of patient position, reflux-inducing maneuvers, and time of the test.

Reproducibility was examined by two different technologists, who performed the test at the same time of the day, using the same reflux provoking maneuver, and with the patient at the same position.

Facilitated reproducibility was studied by examining the same patients by two different technologists immediately after an educational intervention at the central laboratory.

In order to examine potential for decreasing in variability of results, limits of agreement between two duplex scans were studied by changing three elements of the test: time of the day (morning vs afternoon), patient's position (standing vs supine), and reflux initiation (manual vs automatic compression-decompression).

Results: A total of 51 patients were examined by different technologists during four sessions at the central laboratory. At the time of this abstract submission, an additional 68 patients were examined at participating laboratories.

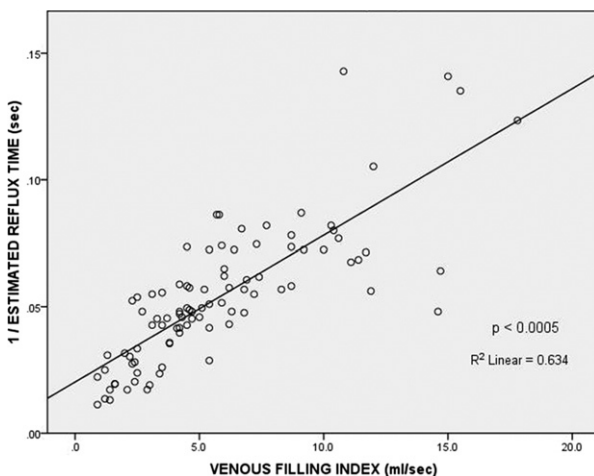
Overall repeatability was 97.7%, with higher values for superficial veins and lower for deep veins. Reproducibility was lower, which indicates a potential for improvement by standardization. This was confirmed by better reproducibility after educational intervention (facilitated reproducibility). The element of the test contributing to most significant variability was the time of the test.

Conclusions: Duplex ultrasound test for venous reflux is repeatable, but the reproducibility can be improved by standardization and training.

Reflux Time on Air Plethysmography is Shortened in Patients with Worsening Chronic Venous Insufficiency

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Background: The venous filling index (VFI), when elevated, is a measure of global venous reflux in the calf. Treatments that successfully abolish reflux normalize the value to under 2 mL/s. Duplex-derived reflux time (RT) at the sapheno-femoral junction (SFJ) has been shown to increase with disease severity, and its reduction has been used as an indicator of treatment success. Our hypothesis is that the stimulus to arrest reflux occurs



when the leg approaches venous capacity. The shorter the RT, the sooner the leg is subjected to the effects of maximal venous hypertension. Our aim was to investigate the direction of the relationship between RT estimated from air plethysmography (APG) and the VFI, a validated indicator of disease severity.

Methods: Ninety-three consecutive patients with primary SFJ reflux (>0.5 seconds) and great saphenous vein reflux (>0.5 seconds) awaiting endovenous treatment were included in the study. Patients with SFJ incompetence, deep venous reflux, or a history of a deep vein thrombosis were excluded. Baseline parameters (median, range) included age (mean, 48 years; range, 22-78 years), averaged great saphenous vein diameter at three sites (mean, 7.5 mm; range, 4-12 mm), and the clinical component of the CEAP classification (C3, C2-C6). A gravitational challenge was applied to an 'emptied' leg with the venous reservoir supported with a sensor cuff at an initial pressure of 6 mm Hg. RT was estimated using the software (ACI Medical, San Marcos, CA) as the time taken to reach 90% of the total venous volume, from the rapid filling phase seen on the monitor.

Results: Median and interquartile range of RT and VFI were 20 seconds (14) and 4.7 mL/s (4.3), respectively. Using APG, estimated reflux time is inversely related to VFI in patients with chronic venous insufficiency ($P < .0005$, Spearman's rho, linear $R^2 = .634$; Fig). Furthermore, shorter reflux time were observed in patients with worsening C scores ($P = .001$) and increasing great saphenous vein diameters ($P < .0005$).

Conclusions: Increasing great saphenous vein diameters may contribute to a faster rate of reservoir refilling (VFI). This results in a shorter RT with a worsening C score. The effects of maximal venous hypertension occur after the end of RT when the reservoir is full, so reflux time measured by air plethysmography may indicate more severe disease. Simultaneous duplex and air plethysmography studies are required to support these findings.

Incidence and Risk Factors for Development of Varicose Veins in the General Population: Edinburgh Vein Study

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Background: Numerous studies have reported on the frequency of varicose veins in the general population (prevalence) and associated lifestyle factors but very few have investigated, longitudinally, the development of new varicose veins (incidence). The aim of this study was to measure the incidence of varicose veins in the adult population and identify factors that increase the future risk of an individual to acquire varicose veins.

Methods: The study was a population cohort in which a random sample of 1566 men and women aged 18 to 64 years, examined at baseline in the Edinburgh Vein Study, were invited to have a 13-year follow-up examination. Assessment included clinical classification of venous disease using CEAP, duplex scanning to assess incompetence of venous valves, body mass index, and questionnaire on venous history and lifestyle factors.

Results: Eight hundred eighty study participants took part in the follow-up study and underwent clinical examination (response rate, 60%). Of the 555 participants who had no trunk varicose veins at baseline, 101 developed C2 trunk varicose veins in any leg during the 13-year follow up. The annual incidence rate of trunk varicose veins was 1.35%. The incidence in men and women was similar with respective rates of 1.31% and 1.39% per year ($P = .45$). The risk of developing new varicose veins appeared to increase with age (incidence rate, 0.73% per annum in 18-34 years; 1.23% in 35-44 years; 1.62% in 45-54 years, and 1.93% in 55-64 years). Increased body mass index was also associated with incidence of varicose veins (incidence rate, 1.06% per annum in underweight; 1.28% normal weight; 1.41% overweight, and 1.54% obese). The incidence rate in those with no family history of varicose veins was 1.07% compared with 1.60% in those with a family history, but this finding was not statistically significant. Number of pregnancies was a significant risk factor, with an incidence rate of 1.24% per year in women who had never been pregnant, increasing to 2.11% per year in those who had been pregnant four times ($P = .02$).

Conclusion: The Edinburgh Vein Study is one of the first to measure the adult incidence of trunk varicose veins and to examine, longitudinally, factors which increase the risk of varicose veins. The associations found between risk factors and incident disease provides stronger evidence of causality than those in prevalence studies. Further analysis of other risk factors, including venous incompetence, and the impact of changing risk factors over time will be presented.

Progression of Chronic Venous Disorders: Results from the Bonn Vein Study

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Background: Chronic venous disorders (CVD) are among the most common diseases in Germany. In the Bonn Vein Study I (BVS I), conducted in 2000, 3072 participants of the general population of the city of Bonn and two rural townships, aged 18 to 79 years, took part in this study (1350 men, 1722 women). Participants were selected via simple random sampling from the registries of residents. In this follow-up study 6.6 years later, the same population was investigated again. The aim was to identify the incidence and

risk factors of progression of pre-existing CVD. In addition, incidence and progression of venous symptoms were documented.

Methods: From May 2007 to September 2008, we contacted all participants of BVS I and invited them for a reinvestigation. The participants answered a standardized questionnaire and were examined by clinical means and by duplex ultrasound in the same way as in BVS I.

Results: The response at follow up after 6.6 years was 84.6%. We reinvestigated 1978 participants. The prevalence for varicose veins (VV) rose from 22.7% to 25.1% and for CVD from 14.5% to 16%. Participants with C-Class C2 as a maximum at BVS I increased to higher C-classes in 19.8% (nonsaphenous VV) and in 31.8% (saphenous VV). In a multivariate analysis, the main risk factors for were age, obesity, and arterial hypertension.

Conclusions: These results show a high incidence of progression of CVD to higher C-classes.

Effect of Compression Therapy on Leg Veins Anatomy: Quantification by 3D Vectorial Modeling from MRI Slices

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Background: Direct mechanical compression of the veins seems to be the main mechanism of action of compression therapy in chronic venous disease. New imaging techniques allow for a quantitative evaluation of the biophysical impact of compression on the 3D anatomy of the leg, particularly on the venous system.

Objective: To use 3D modeling and volume quantification in order to better understand the anatomical effects of compression therapy on the venous system.

Methods: A total of 15 individuals were studied by T2-weighted magnetic resonance image of the calf or thigh in different body positions (supine, prone, upright) before and after application of different stockings and bandages. In every case, the interface pressure was measured by the use of a Picopress pressure transducer. Compression devices producing different pressures and stiffness were assessed. Three-dimensional vectorial models were built with Winsurf software from cross-sectional pictures by manual segmentation of all important anatomical structures (bone, muscles, skin, superficial and deep veins). A realistic interactive 3D vectorial model of the extremity was obtained for each leg, showing the influence of compression on the leg's anatomy not only in a single cross-sectional slice but for the whole calf.

Results: Even low external pressure is able to induce deformations of the underlying muscle compartments. These shifts of tissue go along with changes of venous caliber and are sometimes unrelated to the balance between intravenous pressure and external compression on the skin. Discrepant findings concerning the narrowing of superficial and deep veins are obtained depending on the body position.

Conclusions: Three-dimensional modeling renders clear graphic images of segments of the lower extremity, demonstrating the effect of different kinds of compression on the configuration of the underlying tissue structures, including superficial and deep veins.

Compression Therapy in Mixed Ulcers: Search for a Safe Pressure Range not Affecting Arterial Inflow

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Background: About 15% to 20% of patients with venous leg ulcers have a reduced ankle brachial pressure index (ABPI) causing retarded healing. Compression is able to improve venous hemodynamics in mixed

ulcers but needs to be applied with caution in order not to reduce arterial inflow. This study aimed to define a safe range of compression pressure that does not impede arterial flow.

Methods: In 25 patients with mixed ulcers (ten males, 15 females aged 76.4 ± 10 years), presenting with a mean ABPI of 0.57 ± 0.09 mm Hg and a systolic ankle pressure of 91.8 ± 18.3 mm Hg, skin flow was assessed in the peri-wound area and in the plantar surface of the first toe by means of laser Doppler flowmetry, and toe pressure was measured simultaneously. The measurements were carried out in baseline conditions and after inelastic bandage from the base of the toes to the popliteal area, applied with different pressure ranges of 20 to 30, 30 to 40 and 40 to 50 mm Hg. The pressure exerted by the bandage was continuously measured by a pneumatic device with its flat probe placed next to the laser Doppler probe. The flat, peri-wound laser Doppler probe remained under the bandage, whereas the toe probes were placed distally to the bandage.

Results: Compared with baseline conditions, skin perfusion increases significantly with a bandage pressure of 20 to 30 and 30 to 40 mm Hg, and returns to the baseline level with 40 to 50 mm Hg (Fig 1A). Toe perfusion shows a minor, not significant, decrease with 20 to 30 and 30 to 40 mm Hg, but a significant reduction with 40 to 50 mm Hg (Fig 1B). Toe pressure increases with every pressure step, showing significant differences compared with baseline with 30 to 40 and 40 to 50 mm Hg (Fig 1C).

Conclusions: External compression of 20 to 30 or 30 to 40 mm Hg increases the arterial flow, even in patients with very low ABPI and does not affect the toe pressure as long the individual systolic ankle pressure is not exceeded. Absolute ankle pressure values are more reliable than ABPI to assess the individual risk concerning compression pressure.

Venous Lymphedema

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Background: Lymphatic dysfunction found in swollen limbs with chronic venous disease (CVD), including iliac venous outflow obstruction (venous lymphedema), is often mistaken for primary lymphedema because of an inability to differentiate the etiology by present investigations. The diagnosis of primary lymphedema is often based solely on clinical features, as radioisotope lymphangiogram may be abnormal in both types.

Methods: Radioisotope lymphangiography was performed in 1608 limbs in 819 of 1658 patients with symptoms of CVD over a 13-year period, which underwent intravascular ultrasound-diagnosed/guided iliac vein stenting for iliac venous outflow obstruction. Patients with leg swelling and normal or abnormal lymphangiography were assessed clinically and compared postoperatively in regards to swelling (grade 0-3) and quality of life (CIVIQ score, 20-100).

Results: Lymphangiography was abnormal in 251 limbs in 201 patients (25%), bilateral in 25 of 201 patients (12%); no node visualization in 48 of 251 (19%) limbs and delayed visualization/reduced flow in 203 (81%) limbs. Abnormal lymphangiograms (AbL) occurred in 72 of 443 swollen limbs (16%; median age, 55 years [range, 19-91 years]; female/male ratio, 9/1; left/right limbs ratio, 3/2) and were compared with 240 limbs with normal lymphangiograms (NL). Median follow up was 10 months (range, 2-133 months).

Clinical features thought to be characteristic of primary lymphedema (early onset, bilateral involvement, swelling of dorsum of foot, squaring of toes, stemmer's sign) were present in some limbs of both groups. After iliac vein stenting, grade of swelling improved significantly in both groups AbL and NL (median, 3 [range, 1-3] to 2 [range, 0-3], and 3 [range, 1-3] to 1 [range, 0-3], $P < .0001$, respectively). Complete relief of swelling was found in 9 of 59 limbs (15%) and improvement ≥ 1 grade in 17 of 59 (29%) stented

